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IRO CASE #:XXXXXX

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Right L3-L4 transforaminal epidural injection with selective nerve block

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Physical Medicine and Rehabilitation and Pain Management

REVIEW OUTCOME:
Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Overturned (Disagree)

Medical documentation **supports** the medical necessity of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a XX who sustained a work-related injury on XXXX. The patient was responding XX. He went to pick XX, and he felt pain in his mid to the lower back.

On XXXX, XX, M.D. completed a peer review. The notes from XXXX, included an addendum by XX, M.D. It was noted that the notes documented a change in an MRI findings, representing disc herniations at L4-5 and LS-51. The notes revealed that, however, an MRI had not necessarily been performed before XXXX, and that there was an MRI performed after XXXX. It was noted that it was "not possible to state that the disc herniations seen on the MRI after XXXX, were not related to the index injury. The additional records included, from XXXX, a LEI (lumbar epidural steroid injection) for lumbar radiculopathy. XXXX, note was for a left-sided L4-5 and L5-S1 hemilaminectomy and discectomy procedure performed by XX, M.D. The next set of records included an Employers Report of Injury form XXXX. In that note, reference was made to the patient having lifted XX. "Patient felt pain and stiffness in the middle of his back and numbness in the left leg and thigh area. As of XXXX, it was noted that the individual had been functioning quite well and had occasional stiffness and "no lumbar radicular symptoms. On XXXX, a magnetic resonance imaging of the lumbar spine was performed at XX. The study was interpreted by XX, M.D. The study revealed multifactorial change with moderately severe left lateral recess stenosis with an interval left laminotomy and enhancing left lateral recess epidural fibrosis at the L4-L5 level. An interval left laminotomy with enhancing epidural fibrosis in the lateral recess on the left and adequate capacity in the canal was noted at L5-S1 level. Also, facet arthrosis and ligamentum flavum hypertrophy with minimal disc bulging were noted at L3-L4 level. Reportedly, on XXXX, "the patient helped pick up an XX, immediate pain and stiffness with the baseline changing from 1-5 on a scale of 10, started developing left leg numbness along the lateral thigh with a shooting pain in the lateral lower leg. As of XXXX, and after that, it was noted the patient had an assessment of low back pain, sprain and lumbar

radiculopathy with a grade 1 L4-L5 spondylolisthesis. Another date of injury was XXXX. It was noted the patient indicated that he had XX. He went to xxx, and he felt pain in the mid to lower back. Dr. XX rendered following opinions: the extent of XXXX, injury appeared to have been a sprain/strain and acceleration of pre-existent degenerative abnormalities, in particular at L4-L5. A recurrent disc herniation appeared to have occurred in association with a lifting injury sustained on the date of injury. It was premature to opine as to when the injury should resolve at this point. The pre-existent degenerative conditions were noted at multiple levels. Also, the injury aggravated this condition. The patient's current medical status was recurrent disc herniation with nerve root impingement. There had been slow progress from current treatment. The proper treatment protocol would be up to 10 therapy sessions, intermittent medications including non-steroidal anti-inflammatory drugs (NSAIDS) and/or narcotic analgesics and possible surgical intervention, should the patient not improve satisfactorily. No treatment appeared to exceed ODG. The injury appeared to represent a recurrent disc herniation attributable to XXXX, injury in particular.

On XXXX, the patient was seen by XX, PA-C/XX, M.D. for re-exacerbation of lumbar pain on XXXX. The patient was at work when he XX and cost immediate, mid lumbar pain and stiffness. The patient had a secondary injury on XXXX, while at work when he was involved in an XX. The original pain was at 5/10, which aggravated at 6/10 with 70% patient's current symptoms. The pain aggravated by prolonged standing, sitting, lifting and XX or after increased periods of activities. The lumbar radiculopathy pain was 5/10 and was 30% of the symptoms. The pain went down the left buttocks, posterior thigh and the anterior lower leg. The patient had a left L4-L5 transforaminal epidural steroid injection (TFESI) with selective nerve root block on XXXX, and had 100% relief of the left leg radicular pain with only some residual numbness along the groin and lateral buttocks. His numbness had improved considerably and was bale to walk up to two miles at a time. He attempted to return to work without restrictions on his regular schedule, but this exacerbated his symptoms primarily after having to participate in XX. The patient now reported that he had been developing a right leg electrical pain along the anterior thigh and medial aspect of the thigh radiating into the medial lower leg, and this had become the primary source of symptoms and was the reason why he had to return to a limited duty status at work. Surgical history was notable for vein stripping, lumbar laminectomy, a lumbar discectomy. He was taking Naproxen and Soma. On exam, the lumbar spine was negative for any pain and range of motion (ROM) was also pain-free. The neurological exam of the lower extremities showed 5/5 strength in all muscles. The Babinski, Clonus, Straight leg raise, Valsalva, Pelvic Rock and Patrick tests were all negative bilaterally. The lumbar musculature did not show any atrophy. Deep tendon reflexes (DTR) were 2/4 at bilateral patella and Achilles and 0/4 at bilateral posterior tibialis. On the sensory exam, hypoesthesia was noted at the left L4 and left S1distribution. The x-rays of the pelvis dated XXXX, was normal. On the same day, lumbar spine x-rays showed L4-L5 and L5-S1 discs with decreased disc height with retrolisthesis of L4-L5. Lumbar MRI dated XXXX, showed a right L3-L4 disc bulge with degenerative disc disease. The left L4-L5 had a disc bulge causing moderate spinal canal stenosis. The L5-S1 had left neural foraminal posterior osteophyte. An MRI dated XXXX, was also reviewed. The diagnoses were lumbago with lumbar radiculopathy. Dr. XX stated the prior TFESI provided 100% relief and the patient returned to work without restrictions and the symptoms were exacerbated. The patient still had lumbar facetogenic pain. Dr. XX recommended right L3 TFESI with selective nerve block for diagnostic as well as therapeutic purpose. The treatment plan included continuing with Tramadol, Relafen, Soma and Gabapentin. The patient was recommended for ice/heat application, use of a walker and restricted work. The patient was restricted from XXXXXX during light duty phase.

On XXXX, request for right L3-L4 TFESI with selective nerve block for the time frame from XXXX-XXXX, was raised from XX.

Per Utilization Review dated XXXX, the request for right L3-L4 TFESI with selective nerve block was denied. XX, M.D. denied the request by the following rationale: "*The MRI of the lumbar spine clearly established there was no specific disc lesion or nerve root compromise at the L3 4level. Additionally, there is no pathology noted in this distribution, no evidence of a verifiable radiculopathy either on physical examination or electrodiagnostic study. As such, there is no clear clinical indication for an epidural steroid injection at this level."*

On XXXX, the patient was seen by Mr. XX/Dr. XX for lumbar pain. On exam, the lumbar spine had no scoliosis or kyphosis. There was no atrophy of the lower extremity musculature. There was no lumbosacral tenderness, spasticity bony/soft tissue abnormality. There was no pain throughout the arc of motion. The sacroiliac joint tests were negative for Patrick test, Gaenslen's sign and Pelvic tilt test. The motor exam of the lower extremities was 5/5. The right patellar DTR was 1/4 and left patellar DTR was 2/4. The sensory exam showed hypoesthesia at left L4 and S1 distribution. Dr. XX continued the treatment and re-requested for TFESI with selective nerve block at L3.

On XXXX, request for right L3-L4 TFESI with selective nerve block for the time frame from XXXX-XXXX, was raised from XX.

Per Reconsideration dated XXXX, the request for right L3-L4 TFESI with selective nerve block was non-authorized. XX, M.D., denied the request by the following rationale: "*The request is for an epidural steroid injection at the L3/L4 interspace. The previous injection was completed at the L4 L5 level. There is no objective data demonstrating a disc lesion or nerve root compromise at this level. Understanding there are ongoing complaints of low back and leg pain, there is a lack of specific objective clinical data demonstrating the need for injection at this level. Therefore, this is not clinically indicated. There is no objectified radiculopathy distribution, there is no documentation of conservative care for the specific level, and there is no pathology noted."*

On XXXX, Dr. XX evaluated the patient for lumbar pain radiating to right anterior thigh and anterior lower leg with a dull pain along the lateral lower leg. There was also numbness and tingling along the lateral thigh and lateral lower leg. The numbness and tingling were constant, but the pain was intermittent with a baseline to changes from 0-8 on a scale of 10. Aggravating conditions included walking, prolonged standing or prolonged sitting. Alleviating conditions included short rests, changes in position or shifting his weight. On examination, the patient stood erect without a splinting. No scoliosis or kyphosis was noted. There was no atrophy of the lower extremity musculature. The back had no lumbar or sacral tenderness, spasticity or bony/soft tissue abnormality. ROM was pain free. Motor exam of the lower extremity was unremarkable. The left patellar DTR 1/4 and right patellar DTR was 2/4. There was hypoesthesia at left L4 and S1 distribution. Dr. XX continued Tramadol, Relafen, Soma and gabapentin. Dr. XX stated the patient returned to work without restrictions there was a re-exacerbation of symptoms. He was now experiencing a right leg radicular pain along the anterior and medial thigh as well as the medial lower leg. This electrical pain was constant and variable for which we would like to perform a right L3 for transforaminal epidural injection with selective nerve root block to be both diagnostic and therapeutic. However, Dr. XX denied this injection. However, a board certified radiologist Dr. XX reported that at the L3-4 level there was ligament hypertrophy with facet arthropathy causing right neural foramina! Stenosis and this matched the patient's presentation. Therefore at this point would like to submit for an IRO evaluation on the previously requested L3 for transforaminal epidural injection with selective nerve root block to be both diagnostic and therapeutic for the patient's symptoms. The patient was placed on restricted work until XXXX.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Patient with MRI demonstrating L34 disc lesion. Patient has signs and symptoms of right lumbar radiculopathy at L34 including diminished patellar reflex. Request meets ODG criteria.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X ODG INTEGRATED TREATMENT/DISABILITY DURATION GUIDELINES LOW BACK-LUMBAR AND THORACIC (ACUTE AND CHRONIC)

Epidural steroid injections (ESIs), therapeutic

Recommended as a possible option for short-term treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) with use in conjunction with active rehab efforts. Not recommended for spinal stenosis or for nonspecific low back pain. See specific criteria for use below.

See the Neck Chapter, where ESIs are not recommended based on recent evidence, given the serious risks of this procedure in the cervical region and the lack of quality evidence for sustained benefit.

Criteria for the use of Epidural steroid injections:
Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, the reduction of medication use and the avoidance of surgery, but this treatment alone offers no significant long-term functional benefit.
(1) Radiculopathy (due to herniated nucleus pulposus, but not spinal stenosis) must be documented. Objective findings on examination need to be present. Radiculopathy must be corroborated by imaging studies and/or electrodiagnostic testing.
(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs, muscle relaxants, and neuropathic drugs).
(3) Injections should be performed using fluoroscopy (live x-ray) and injection of contrast for guidance.
(4) *Diagnostic Phase:* At the time of initial use of an ESI (formally referred to as the "diagnostic phase" as initial injections indicate whether success will be obtained with this treatment intervention), a maximum of one to two injections should be performed. A repeat block is not recommended if there is inadequate response to the first block (< 30% is a standard placebo response). A second block is also not indicated if the first block is accurately placed unless: (a) there is a question of the pain generator; (b) there was possibility of inaccurate placement; or (c) there is evidence of multilevel pathology. In these cases, a different level or approach might be proposed. There should be an interval of at least one to two weeks between injections.
(5) No more than two nerve root levels should be injected using transforaminal blocks.
(6) No more than one interlaminar level should be injected at one session.
(7) *Therapeutic phase:* If after the initial block/blocks are given (see "Diagnostic Phase" above) and found to produce pain relief of at least 50-70% pain relief for at least 6-8 weeks, additional blocks may be supported. This is generally referred to as the "therapeutic phase." Indications for repeat blocks include acute exacerbation of pain, or new onset of radicular symptoms. The general consensus recommendation is for no more than 4 blocks per region per year. (CMS, 2004) (Boswell, 2007)
(8) Repeat injections should be based on continued objective documented pain relief, decreased need for pain medications, and functional response.
(9) Current research does not support a routine use of a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections for the initial phase and rarely more than 2 for therapeutic treatment.
(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or sacroiliac blocks or lumbar sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.
(11) Cervical and lumbar epidural steroid injection should not be performed on the same day. (Doing both injections on the same day could result in an excessive dose of steroids, which can be dangerous, and not worth the risk for a treatment that has no long-term benefit.)
(12) Excessive sedation should be avoided.

Radiculopathy symptoms are generally due to herniated nucleus pulposus or spinal stenosis, but ESIs have not been found to be as beneficial a treatment for the latter condition. According to SPORT, ESIs are associated with less improvement in spinal stenosis. (Radcliff, 2013)

Short-term symptoms: The American Academy of Neurology recently concluded that epidural steroid injections may lead to an improvement in radicular pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months. (Armon, 2007) Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program. There is little information on improved function or return to work. There is no high-level evidence to support the use of

epidural injections of steroids, local anesthetics, and/or opioids as a treatment for acute low back pain without radiculopathy. (Benzon, 1986) (ISIS, 1999) (DePalma, 2005) (Molloy, 2005) (Wilson-MacDonald, 2005)

Use for chronic pain: Chronic duration of symptoms (> 6 months) has also been found to decrease success rates with a threefold decrease found in patients with symptom duration > 24 months. The ideal time of either when to initiate treatment or when treatment is no longer thought to be effective has not been determined. (Hopwood, 1993) (Cyteval, 2006) Indications for repeating ESIs in patients with chronic pain at a level previously injected (> 24 months) include a symptom-free interval or indication of a new clinical presentation at the level.

For spinal stenosis: The use of epidural steroid injection (ESI) in patients with lumbar spinal stenosis is common, but there is little evidence in the literature to demonstrate its long-term benefit. Despite equivalent baseline status, ESIs are associated with significantly less improvement at 4 years among all patients with spinal stenosis. Furthermore, ESIs were associated with longer duration of surgery and longer hospital stay. There was no improvement in outcome with ESI whether patients were treated surgically or nonsurgically. There was no distinct surgical avoidance noted with ESI. (Radcliff, 2013) This systematic review found the data was limited to suggest that ESI is effective in lumbar spinal stenosis. (Bresnahan, 2013) An RCT addressed the use of ESIs for treatment of spinal stenosis, and there was no statistical difference except in pain intensity and Roland Morris Disability Index and this was at two weeks only. (Koc, 2009) According to the APS/ ACP guidelines, ESIs are not for nonspecific low back pain or spinal stenosis. (Chou, 2008) According to a high-quality RCT, in the treatment of symptoms of lumbar spinal stenosis, epidural injections of glucocorticoids plus lidocaine offered minimal or no benefit over epidural injections of lidocaine alone at 6 weeks. At 3 weeks, the glucocorticoid-lidocaine group had greater improvement than the lidocaine-alone group, but the differences were clinically insignificant. Despite a rapid increase in the use of epidural glucocorticoid injections for lumbar spinal stenosis, there is little evidence of effectiveness from clinical trials. (Friedly, 2014)

Transforaminal approach: Some groups suggest that there may be a preference for a transforaminal approach as the technique allows for delivery of medication at the target tissue site, and an advantage for transforaminal injections in herniated nucleus pulposus over translaminar or caudal injections has been suggested in the best available studies. (Riew, 2000) (Vad, 2002) (Young, 2007) This approach may be particularly helpful in patients with large disc herniations, foraminal stenosis, and lateral disc herniations. (Colorado, 2001) (ICSI, 2004) (McLain, 2005) (Wilson-MacDonald, 2005) Two recent RCTs of caudal injections had different conclusions. This study concluded that caudal injections demonstrated 50% pain relief in 70% of the patients, but required an average of 3-4 procedures per year. (Manchikanti, 2011) This higher quality study concluded that caudal injections are not recommended for chronic lumbar radiculopathy. (Iversen, 2011) Transforaminal epidural steroid injections, despite being generally regarded as superior to interlaminar injections, are not significantly better in providing pain relief or functional improvement, according to a new systematic review. (Chien, 2014)

Fluoroscopic guidance: Fluoroscopic guidance with use of contrast is recommended for all approaches as needle misplacement may be a cause of treatment failure. (Manchikanti, 1999) (Colorado, 2001) (ICSI, 2004) (Molloy, 2005) (Young, 2007)

Factors that decrease success: Decreased success rates have been found in patients who are unemployed due to pain, who smoke, have had previous back surgery, have pain that is not decreased by medication, and/or evidence of substance abuse, disability or litigation. (Jamison, 1991) (Abram, 1999) Research reporting effectiveness of ESIs in the past has been contradictory, but these discrepancies are felt to have been, in part, secondary to numerous methodological flaws in the early studies, including the lack of imaging and contrast administration. Success rates also may depend on the technical skill of the interventionalist. (Carette, 1997) (Bigos, 1999) (Rozenberg, 1999) (Botwin, 2002) (Manchikanti, 2003) (CMS, 2004) (Delport, 2004) (Khot, 2004) (Buttermann, 2004) (Buttermann2, 2004) (Samanta, 2004) (Cigna, 2004) (Benzon, 2005) (Dashfield, 2005) (Arden, 2005) (Price, 2005) (Resnick, 2005) (Abdi, 2007) (Boswell, 2007) (Buenaventura, 2009) Also see Epidural steroid injections, "series of three" and Epidural steroid injections, diagnostic. ESIs may be helpful with radicular symptoms not responsive to 2 to 6 weeks of conservative therapy. (Kinkade,

2007) Epidural steroid injections are an option for short-term pain relief of persistent radiculopathy, although not for nonspecific low back pain or spinal stenosis. (Chou, 2008) As noted above, injections are recommended if they can facilitate a return to functionality (via activity and exercise). If post-injection physical therapy visits are required for instruction in these active self-performed exercise programs, these visits should be included within the overall recommendations under Physical therapy, or at least not require more than 2 additional visits to reinforce the home exercise program.

With discectomy: Epidural steroid administration during lumbar discectomy may reduce early neurologic impairment, pain, and convalescence and enhance recovery without increasing risks of complications. (Rasmussen, 2008) Not recommended post-op. The evidence for ESI for post lumbar surgery syndrome is poor. (Manchikanti, 2012)

Patient selection: Radiculopathy must be documented, as indicated in the ODG criteria. In addition, ESIs are more often successful in patients without significant compression of the nerve root and, therefore, in whom an inflammatory basis for radicular pain is most likely. In such patients, a success rate of 75% renders ESI an attractive temporary alternative to surgery, but in patients with significant compression of the nerve root, the likelihood of benefiting from ESI is low (26%). This success rate may be no more than that of a placebo effect, and surgery may be a more appropriate consideration. (Ghahreman, 2011) Injections for spinal pain have high failure rates, emphasizing the importance of patient selection. Individuals with centralized pain, such as those with fibromyalgia and chronic widespread pain, and poorly controlled depression, may be poor candidates. (Brummett, 2013)

MRIs: According to this RCT, the use of MRI before ESIs does not improve patient outcomes and has a minimal effect on decision making, but the use of MRI might have reduced the total number of injections required and may have improved outcomes in a subset of patients. Given these potential benefits as well as concerns related to missing important rare contraindications to epidural steroid injection, plus the small benefits of ESIs themselves, ODG continues to recommend that radiculopathy be corroborated by imaging studies and/or electrodiagnostic testing. (Cohen, 2012)

Fracture risk: Lumbar ESIs are associated with an increased risk for spinal fracture. Each single additional ESI increased the risk for fracture by 21%, with an increasing number of ESIs associated with an increasing likelihood of fracture. Use of ESIs seems to promote deterioration of skeletal quality. This definable fracture risk should be balanced with the best available evidence regarding the long-term efficacy of ESIs, which is limited. Clinicians should consider these findings before prescribing ESIs for elderly patients. (Mandel, 2013)

Sedation: The use of sedation during ESI remains controversial. Sedation is less often indicated during lumbar ESI compared with cervical ESI because fewer patients experience a vasovagal reaction, which is likely an indicator of anxiety. (Trentman, 2009) According to a multidisciplinary collaboration led by the FDA, heavy sedation should be avoided in favor of sedation light enough to allow the patient to communicate during the procedure. (Rathmell, 2015) For a more extensive discussion, see the Pain Chapter. See also the Neck Chapter.

Recent research: An updated Cochrane review of injection therapies (ESIs, facets, trigger points) for low back pain concluded that there is no strong evidence for or against the use of any type of injection therapy, but it cannot be ruled out that specific subgroups of patients may respond to a specific type of injection therapy. (Staal-*Cochrane*, 2009) Recent studies document a 629% increase in expenditures for ESIs, without demonstrated improvements in patient outcomes or disability rates. (Deyo, 2009) There is fair evidence that epidural steroid injection is moderately effective for short-term (but not long-term) symptom relief. (Chou3, 2009) This RCT concluded that caudal epidural injections containing steroids demonstrated better and faster efficacy than placebo. (Sayegh, 2009) In this RCT there were no statistically significant differences between any of the three groups at any time points. This study had some limitations: only one type of steroid in one dose was tested; the approach used was caudal and transforaminal injections might provide superior results. (Weiner, 2012) Effects are short-term and minimal. At follow-up of up to 3 months, epidural steroids were associated with statistically significant reductions in mean leg pain and mean disability score, but neither of these short-term improvements reached the threshold for clinical significance. There were no significant

differences in either leg pain or disability at the 12-month follow-up. (Pinto, 2012) According to this systematic review, ESIs without the drug (epidural nonsteroid injections), often used as a placebo treatment, were as effective as ESIs and better than no epidural injections. (Bicket, 2013) This meta-analysis suggested that ESI did not improve back-specific disability more than a placebo or other procedure long-term (6 months), and did not significantly decrease the number of patients who underwent subsequent surgery. (Choi, 2013) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014) This study shows that ESIs had a significant beneficial effect as an additional treatment for lumbosacral radicular syndrome in general practice, but the effect was too small to be considered clinically relevant to patients, so the authors do not recommend ESIs as a regular intervention in general practice. (Spijker-Huiges, 2014) A high-quality RCT concluded that gabapentin and ESIs for radicular pain both resulted in modest improvements in pain and function, which persisted through three months. Some differences favored ESIs, but these tended to be small and transient. They recommended a trial with neuropathic drugs as a reasonable first line treatment option. (Cohen, 2015) The AHRQ comparative effectiveness study on injection therapies for LBP concluded that ESIs for radiculopathy were associated with immediate improvements in pain and might be associated with immediate improvements in function, but benefits were small and not sustained, and there was no effect on long-term risk of surgery. Evidence did not suggest that effectiveness varies based on injection technique, corticosteroid, dose, or comparator. Limited evidence suggested that epidural corticosteroid injections are not effective for spinal stenosis or nonradicular back pain. (Chou, 2015) In another systematic review, evidence was only robust for positive effects in patients with chronic radiculopathy, with statistically significant effects on immediate (5 days to ≤2 weeks) improvement in pain, and short-term (>2 weeks to ≤3 months) surgery risk. (Chou, 2015b)